In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-143V

Filed: June 2, 2016

KATELYN GARNER,	*	TO BE PUBLISHED
	*	
Petitioner,	*	Special Master Hamilton-Fieldman
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Gardasil; Human Papillomavirus (HPV) Vaccine; Statute of Limitations; Premature Ovarian Failure (POF); Primary Ovarian Insufficiency (POI); First Symptom or Manifestation of Onset; Menstrual Cycle; Dismissal.
Respondent.	*	

Mark Krueger, Krueger & Hernandez, SC, Baraboo, WI, for Petitioner.
Lara Englund, United States Department of Justice, Washington, DC, for Respondent.

DECISION[1]

This is an action by Katelyn Garner ("Petitioner") seeking an award under the National Vaccine Injury Compensation Program (hereinafter "Program").[2] Respondent contends that the petition was untimely filed, and as such should be dismissed. For the reasons set forth below, the undersigned concludes that the petition was untimely filed, and it is therefore hereby dismissed.

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the purposes espoused in the E-Government Act of 2002. *See* 44 U.S.C. § 3501 (2012). Each party has 14 days to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b).

[2] The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (hereinafter "Vaccine Act"), provides the statutory provisions governing the Program.

I. FACTUAL BACKGROUND

Petitioner was born on December 5, 1994 at St. Luke's Hospital in Chesterfield, Missouri. Pet'r's Ex. 1 at 1, ECF No. 6-2. Other than a tonsillectomy and adenoidectomy in December 2004, which she underwent to treat her recurrent tonsillitis, Pet'r's Ex. 3 at 21-25, ECF No. 6-4, Petitioner's pre-vaccine medical history is unremarkable, *see generally id.* Through 2007, her pubertal development appears to have been normal: onset of breast and pubic hair development occurred in 2006 and 2007, when Petitioner was in sixth and seventh grade. *Id.* at 16.

She was administered Gardasil vaccinations on August 9, 2007, August 11, 2008, and April 13, 2009. Pet'r's Ex. 2 at 1, ECF No. 6-3; Pet'r's Ex. 3 at 14, 29.

At well-child visits on August 10, 2006 and August 9, 2007, when Petitioner was 11 and 12 years old, respectively, no abnormalities in pubertal development were noted.[3] Pet'r's Ex. 3 at 43-44. At her 12-year well-check on August 9, 2007, Petitioner was noted to have had a Tanner developmental stage of "III-IV". *Id.* at 44. At her 13-year-old well-check visit on August 11, 2008, her pediatrician noted that she was at Tanner Stage II,[4] one to two stages lower than she had been the year before. *Id*. Her pediatrician also noted the following regarding the following regarding Petitioner's menstruation: "Menses – X1 ? 1 yr ago." *Id*.

At her 14 year-old well-check visit on October 2, 2009, Petitioner was documented to have been Tanner Stage III. *Id.* at 45. Her pediatrician noted that she had never had a menstrual cycle. *Id*.

The record contains no documentation regarding well-child visits for Petitioner's 15th year, though Petitioner's mother has averred that she "took [Petitioner] annually for pediatric visits." Pet'r's Ex. 5 at 1, ECF No. 6-6. Documentation of a visit on July 25, 2011 does not

[3] The undersigned was unable to decipher many of the records from East Louisville Pediatrics, the notes from which were largely illegible. *See, e.g.*, Pet'r's Ex. 3 at 9.

[4] Pubertal development is measured by assessing an individual's stages of puberty using the Tanner growth chart, which is "based on pubic hair growth, development of genitalia in boys, and breast development in girls." Tanner stage, *Stedman's*. For purposes of the ACOG criteria, the undersigned considers Tanner stages I (child) and II (prepubertal) as showing "no signs of pubertal development," and Tanner stags III (early pubescent) and IV (late pubescent) as showing such signs. Dr. Frankfurter testified that a young woman who has never menstruated and who has no signs of secondary sexual development by age 13 should be evaluated. Tr. at 377.

reflect any abnormal development, but it makes no mention of whether Petitioner experienced menarche.[5] Pet'r's Ex. 8 at 28, ECF No. 8-2.

On March 14, 2012, when Petitioner 17 years old, her pediatrician at East Louisville Pediatrics noted that Petitioner had never had a menstrual cycle, and referred her to a gynecological specialist. Pet'r's Ex. 3 at 38. Petitioner was seen by gynecologist Dr. Meredith B. Loveless on April 17, 2012 for an evaluation of primary amenorrhea.[6] *Id.* at 16; Pet'r's Ex. 7 at 1-2, ECF No. 6-8. As of this visit, Dr. Loveless documented that Petitioner had never had a cycle. Pet'r's Ex. 7 at 1-2. Although she was sexually active, Petitioner had never used contraception. *Id*. She was noted to have had "Tanner Stage 5 breast and pubic hair development." *Id*. No evidence of acne, hirsutism or acanthosis nigricans was noted, and no other abnormalities were noted. *Id*.

On May 1, 2012, Petitioner was treated again by Dr. Loveless. Pet'r's Ex. 3 at 20; Pet'r's Ex. 6 at 108, ECF No. 6-7. Her treatment records document that she had a "significantly elevated" FSH level of 81.9. Pet'r's Ex. 6 at 108. Her chromosomal analysis was normal. *Id*. Dr. Loveless diagnosed Petitioner with primary ovarian insufficiency ("POI") [7] and prescribed estrogen replacement. *Id*.

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[5] Menarche is "the establishment or beginning of menstruation." Menarche, *Dorland's Illustrated Medical Dictionary* (32nd ed. 2012) (hereinafter "*Dorland's*"). Menstruation is "the cyclic, physiologic discharge through the vagina of blood and mucosal tissues from the nonpregnant uterus; it is under hormonal control and normally recurs, usually at approximately four-week intervals, in the absence of pregnancy during the reproductive period (puberty through menopause of the female of the human." Menstruation, *Dorland's*.

[6] Amenorrhea is "absence or abnormal stoppage of the menses." Amenorrhea, *Dorland's*. Primary amenorrhea is "failure of menstruation to occur at puberty." Primary Amenorrhea, *Dorland's*. Secondary amenorrhea is "cessation of menstruation after it has once been established at puberty." Secondary Amenorrhea, *Dorland's*.

[7] Although the parties and the undersigned initially used the term, "premature ovarian failure" or "POF" to define Petitioner's injury—it became clear from the literature filed by the experts that POI "is the preferred term for the condition that was previously referred to as [POF]. . . . The condition is considered to be present when a woman who is less than 40 years old has had amenorrhea for 4 months or more, with two serum FSH levels (obtained at least 1 month apart) in the menopausal range." *See* Pet'r's Ex. 15, Tab 1 at 1, *Culligan v. Sec'y of HHS*, No. 14-318V ECF No. 53-2 (Lawrence Nelson, *Primary Ovarian Insufficiency*, 360 New Eng. J. Med. 606, 606 (2009)) (hereinafter "Nelson" with pincites to Petitioner's pagination); *see also* Resp't's Ex. A.29, ECF No. 67-1 (also providing Nelson). Therefore, the undersigned will refer to the condition as POI.

After a visit on July 26, 2012, Dr. Loveless again noted Petitioner's diagnosis of POI. Pet'r's Ex. 3 at 17; Pet'r's Ex. 6 at 105-06. Dr. Loveless noted that Petitioner had undergone two FSH tests that were "significantly elevated," which provided additional confirmation of the POI diagnosis. Pet'r's Ex. 3 at 17; Pet'r's Ex. 6 at 90, 97. All testing for autoimmune etiology returned normal, and Petitioner's "Period type is normal." *Id*. Vitamin D studies and thyroid levels were normal. *Id.* An ultrasound revealed that Petitioner had a small uterus with very small ovaries. *Id*. Petitioner was continued on estrogen replacement, and Dr. Loveless recommended she undergo fragile X mutation testing. *Id*.

On September 6, 2012, Petitioner was treated by geneticist Alexander Asamoah after having been referred by her pediatrician for assessment of POI. Pet'r's Ex. 4 at 2, ECF No. 6-5. Dr. Asamoah noted that "[w]hen [Petitioner] was approximately 12 to 13 years old, she experienced one day of spotting, but has not had a period since this time." *Id*. At the time of the September 2012 visit, Petitioner was on an estrogen patch, which had resulted in some breast development. *Id*. Dr. Asamoah described Petitioner as "a 17-year, 9-month-old female with [POI] and delayed breast development." *Id*. at 3. She had no chromosomal abnormalities. *Id*. at 4

On October 25, 2012, Dr. Loveless renewed Petitioner's prescription for estradiol, an estrogen patch. Pet'r's Ex. 6 at 2-3. Dr. Loveless noted that Petitioner's development appeared normal, that her development was at a Tanner Stage IV, and that she had primary amenorrhea and POI. *Id*. at 5-8. When she saw Dr. Loveless again on January 31, 2013, Petitioner had begun hormone replacement with "Vivelle-Dot," which had resulted in some breast development but no vaginal bleeding. *Id*. at 10-16.

At a visit on May 9, 2013, ultrasound examination revealed a normally-sized uterus and ovaries. Pet'r's Ex. 6 at 17- 28. Dr. Loveless noted that Petitioner "began to have vaginal bleeding in March lasting for about 9 days and spotting. In April she had spotting on the fourth of [sic] the fifth and then again on the 15th or 16th." *Id*. at 23. Dr. Loveless subsequently described this as "spontaneous onset of menses." *Id*. at 24.

Petitioner subsequently experienced semi-regular menstrual periods. *Id*. at 49. After menstruating in March of 2013, she menstruated in June 2013, September 2013, November 2013, December 2013, January 2014, and February 2014. Pet'r's Ex. 6 at 49.

II. PROCEDURAL BACKGROUND

On February 11, 2015, Petitioner filed the present action alleging that the Human Papillomavirus vaccinations ("Gardasil" or "HPV" vaccines) administered to her on August 9, 2007, August 11, 2008, and April 13, 2009 caused her to suffer from POI. Pet., ECF No. 1.

This case was identified for inclusion with other POI cases in an "omnibus proceeding" established to address the question of what constitutes the first symptom or manifestation of POI. *See* Pet'r's Status Report (Oct. 1, 2014), *Culligan*, ECF No. 23. The answer to this question is integral to the undersigned's determination of whether each petitioner had filed her claim within the statute of limitations. *See* 42 U.S.C. § 300aa-16(a)(2) (2012) (requiring that petitions be filed prior to "the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of injury").

The lead case in the proceeding was *Culligan.*[8] In *Culligan*, Respondent opposed entitlement to compensation because the first symptom of the petitioner's POI was oligomenorrhea,[9] which she had experienced more than three years prior to the filing of her claim, making it untimely under 42 U.S.C. § 300aa-16(a)(2). *See* Resp't's Rule 4(c) Report at 3-4, *Culligan*, ECF No. 20.

At a *Culligan* status conference held on September 23, 2014, the undersigned discussed with the parties the necessity of establishing the date that the statute of limitations began to run in *Culligan* and other cases alleging an injury of POI caused by Gardasil in order to assess the timeliness of the claims. *See* Scheduling Order (Sept. 25, 2014) at 1, *Culligan*, ECF No. 22. The undersigned directed the petitioner in *Culligan*'s counsel, Mark Krueger, who is also counsel in the instant case, to begin the process of identifying other POI claimants for inclusion in an omnibus proceeding focused on the question of timeliness.[10] *Id*.

On October 1, 2014, Mr. Krueger filed a status report in which he identified eight POI cases[11] to be included in the undersigned's assessment of timeliness. *See* Pet'r's Status Report

[8] Once *Culligan* had been designated as the lead case, all of the filings for the onset proceedings were completed in the *Culligan* case, and not in the trailing cases. This section of the procedural history is therefore derived from the *Culligan* case. Citations to the *Culligan* record are so noted.

[9] Oligomenorrhea is defined as "menstrual flow happening less often than normal, defined as at intervals of 35 days to 6 months; called also *infrequent menstruation*." Oligomenorrhea, *Dorland's*.

[10] Mr. Krueger is counsel for all but one of the petitioners in the omnibus proceeding.

[11] Other than the instant case, Petitioner identified *Culligan*; *Alexander v. Sec'y of HHS*, 14-868V; *Tilley v. Sec'y of HHS*, 14-818V; *Fishkis v. Sec'y of HHS*, 14-527V; *Lydia McSherry v. Sec'y of HHS*, 14-154V; *Meghan McSherry v. Sec'y of HHS*, 14-153V; *Stone v. Sec'y of HHS*, 13-289V. Pet'r's Status Report (Oct. 1, 2014) at 1, ECF No. 23.

(Oct. 1, 2014), *Culligan*. Petitioner subsequently named *Culligan* as the "test case" for timeliness. *See* Pet'r's Status Report (Nov. 5, 2014) at 1, ECF No. 25.

Another status conference was held on November 20, 2014, during which the parties agreed that "in all pending [POI] cases . . . an expert hearing [would] be held to address the question of what constitutes 'the first symptom or manifestation of [POI] onset recognized as such by the medical profession at large.'" Scheduling Order (Nov. 24, 2014) at 1, *Culligan*, ECF No. 26 (citing *Cloer v. Sec'y of HHS*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc)). The undersigned explained that a timeliness determination would be made on the basis of the evidence presented at the *Culligan* hearing; similar hearings would *not* be conducted in the other POI cases, all of which would trail *Culligan* for purposes of timeliness determinations. *Id*. The undersigned also added four additional POI cases[12] to the list of cases set to trail *Culligan*. *Id*. The undersigned also ordered that all parties seeking to be joined in the omnibus proceeding consent to share their medical records, *see* Scheduling Order (Nov. 24, 2014) at 2, *Culligan*, and all parties later obliged.

The parties and the undersigned proceeded to identify questions for the experts (to be researched and answered before the hearing) regarding the nature and timing of the first symptom or manifestation of onset of POI in the aforementioned cases. *See, e.g.*, Order (Feb. 18, 2015) at 1, *Culligan*, ECF No. 37; Scheduling Order (Jan. 30, 2015) at 1, *Culligan*, ECF No. 36; Pet'r's Status Report (Dec. 29, 2014) at 1, *Culligan*, ECF No. 31; Scheduling Order (Nov. 24, 2014) at 2, *Culligan*; Resp't's Status Report (Oct. 28, 2014) at 1, *Culligan,* ECF No. 24. The parties and their experts ultimately agreed that, except in *Culligan*, in which the entire medical record would be considered by the experts, the experts would "offer opinions regarding the onset issues in the trailing cases by considering the facts of those cases as hypotheticals." Joint Status Report (Jan. 20, 2015) at 1, *Culligan*, ECF No. 33. To facilitate this process, Petitioner filed summaries of the facts of all twelve POI cases. *See* Pet'r's Ex. 9, *Culligan*, ECF No. 34-2.[13] Except in *Culligan*, the experts were to rely on the factual summaries, in lieu of the medical records themselves, to articulate their opinions regarding timeliness. *See* Joint Status Report (Jan. 20, 2015) at 1, *Culligan*.

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[12] The four added cases were *Chenowith v. Sec'y of HHS*, 14-996V; *Bello v. Sec'y of HHS*, 13-349V; *Olivia Meylor v. Sec'y of HHS*, 10-771V; *Madelyne Meylor v. Sec'y of HHS*, 10-770V. *Id.* The petitioners in these cases were all represented by Mr. Krueger.

[13] A factual summary for another trailing POF case–*Smith*, 14-1107V –was also filed in *Culligan*. *See* Order Appendix (Feb. 23, 2015) at 2-3, *Culligan*, ECF No. 39-1; *see also* Order (Jan. 30, 2015) at 1-2, *Culligan*, ECF No. 36; Order (Jan. 26, 2015), *Culligan*, ECF No. 35. The petitioner in *Smith* was represented by different counsel.

At a status conference held on January 28, 2015, the undersigned set deadlines for the parties' expert reports regarding timeliness. *See* Order (Jan. 30, 2015) at 2, *Culligan*. The experts were directed to address all of the identified timeliness questions separately, "on a question-by-question basis." *Id*. at 1.

On February 19 and March 3, 2015, three additional cases,[14] all filed by Mr. Krueger, were added to the list of POI trailing cases. *See* Scheduling Order (Mar. 3, 2015) at 1, *Culligan*, ECF No. 45; Scheduling Order (Feb. 19, 2015) at 1, *Culligan*, ECF No. 38. Mr. Krueger subsequently filed factual summaries of the three new cases. *See* Pet'r's Exs. 10, 11, 12, *Culligan*, ECF Nos. 40-2, 41-2, 44-2.

On March 12, March 13, and April 29, 2015, Petitioner filed expert reports and supporting medical literature, all of which were purportedly limited to the issue of timeliness. *See* Pet'r's Ex. 13, *Culligan*, ECF Nos. 47-2 to 51-6; Pet'r's Ex. 15, *Culligan*, ECF Nos. 53-1 to 54-3; Pet'r's Ex. 17, *Culligan*.[15] The expert reports were authored by Dr. Felice Gersh and Dr. Orit Pinhas-Hamiel. *See* Pet'r's Ex. 13, Tab 1, *Culligan*; Pet'r's Ex. 15, Tab 1, *Culligan*. The reports filed by Drs. Gersh and Hamiel reflected that they had reviewed the medical records underlying all of the POI cases. *See* Pet'r's Ex. 13, Tab 1 at 12-13, *Culligan*; Pet'r's Ex. 15, Tab 1 at 17, *Culligan*.

The undersigned convened a status conference on April 1, 2015, after having reviewed Petitioner's expert reports. *See* Scheduling Order (Apr. 2, 2015) at 1, *Culligan,* ECF No. 55. The undersigned noted that, "notwithstanding the fact that Petitioner's onset experts have now reviewed the medical records associated with every [POI] case, Respondent's onset expert(s) will review only the cases' factual summaries, the *Culligan* record, and Respondent's list of hypothetical questions." *Id*. Also, having expressed some concern about the extent to which Petitioner's expert reports reflected an understanding of the relevant question regarding timeliness, the undersigned reiterated the following:

> [T]he relevant date, for purposes of assessing onset under *Cloer*, is *not* the first point in time at which a definitive diagnosis could have been made; rather, it is the time at which the first symptom or manifestation of the allegedly vaccine-caused injury occurred. The onset experts must make this assessment with the benefit of hindsight, rather than placing themselves in the shoes of the treating,

[14] The cases were *Brayboy v. Sec'y of HHS*, 15-183V; *Garner v. Sec'y of HHS*, 15-143V; and *Vakalis v. Sec'y of HHS*, 15-134V.

[15] Petitioner filed Exhibit 17 via compact disc. *See* Notice of Intent to File on Compact Disc (Apr. 29, 2015), *Culligan*, ECF No. 56.

> diagnosing physicians. The parties are directed to address this issue as specifically as possible in their pre-hearing briefs.

Id. (full citation omitted).

Respondent then filed an expert report regarding timeliness, as well as relevant medical literature, on May 8, May 28, and June 1, 2015. Resp't's Ex. A to A.32, *Culligan,* ECF Nos. 57-1 to 59-6, 63-1 to 63-3, 66-1 to 67-4. Respondent's expert report was authored by Dr. David Frankfurter. Resp't's Ex. A at 6, *Culligan*.

At a status conference held on May 14, 2015, Respondent confirmed that, in preparing his expert report, Dr. Frankfurter had reviewed only the factual summaries submitted by Petitioner (and the medical record from *Culligan*). *See* Order (May 15, 2015) at 1, *Culligan,* ECF No. 61. Mr. Krueger agreed that, notwithstanding the fact that his experts had reviewed all of the medical records in all of the POI cases, "his experts would be referring to the factual summaries rather than to the medical records themselves" at the timeliness hearing. *Id*.

The parties filed their pre-hearing briefs simultaneously on June 1, 2015, *see* Pet'r's Prehearing Submissions, *Culligan,* ECF No. 65; Resp't's Prehearing Submissions, *Culligan,* ECF No. 69; and the hearing took place on June 16 and 17, 2015, *see* Minute Entry (June 18, 2015), *Culligan*. Petitioner's experts, Drs. Gersh and Hamiel, and Respondent's expert, Dr. Frankfurter, testified. Tr. at 4, 255, *Culligan,* ECF Nos. 81, 83.

On July 1, 2015, the undersigned issued an order identifying nine POI cases[16] "as presumptively precluded under the applicable statute of limitations." Order (July 1, 2015) at 1, *Culligan,* ECF No. 79. *Culligan* was included among the presumptively precluded cases. *Id*. The undersigned also identified six cases[17] that appeared to have been timely filed. *Id*. Having apprised the parties of these preliminary conclusions, the undersigned granted them additional time to file status reports identifying the cases in which they intended to contest this determination, and explaining what they had identified as the first symptom or manifestation of onset in each of those cases. *Id*. at 2.

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[16] The instant case, as well as *Culligan*, *Chenowith*, *Fishkis*, *Garner*, *Lydia McSherry*, *Meghan McSherry*, *Madelyne Meylor*, and *Laughlin*. Order (July 1, 2015) at 1.

[17] *Alexander*, *Bello*, *Brayboy*, *Olivia Meylor*, and *Vakalis*. *Id.* The undersigned also identified as timely *Smith*, a trailing POF case that had been filed by a different attorney. *Id.* In *Tilley*, the undersigned directed the parties to file additional briefs regarding timeliness. *Id.*

On August 28, 2015, Respondent filed a status report in which she stated that she did not intend to contest the undersigned's preliminary findings in any of the presumptively timely cases filed by Mr. Krueger. Resp't's Status Report (Aug. 28, 2015) at 1, *Culligan,* ECF No. 84. In status reports filed on September 2 and 30, 2015, Petitioner argued that all of the preliminarily precluded cases were, in fact, timely. *See* Pet'r's Status Report (Sept. 2, 2015) at 2-7, *Culligan*, ECF No. 85 (addressing *Culligan*, *Chenowith*, *Garner*, *Lee*, *Lydia McSherry*, and *Madelyne Meylor*); Pet'r's Status Report (Sept. 30, 2015) at 1-2, *Culligan,* ECF No. 87 (addressing *Fishkis*, *Meghan McSherry*, *Stone*).

At a status conference held on October 13, 2015, the undersigned "informed the parties that, for purposes of an onset determination, the [POI] cases [would] be divided [into] two groups: petitioners who never menstruated . . . and the rest of the [POI] petitioners." *See* Scheduling Order (Oct. 14, 2015) at 1, *Culligan,* ECF No. 88.

Relevant post-hearing briefing[18] concluded on January 20, 2016. *See* Pet'r's Post Hr'g Br., *Culligan,* ECF No. 91; Resp't's Post Hr'g Brs., *Culligan,* ECF No. 94; Pet'r's Post Hr'g Reply Br., *Culligan,* ECF No. 95. Petitioner's claim is now ready for a determination of the first symptom or manifestation of onset of the alleged vaccine-related injury; and, relatedly, whether the Vaccine Act's statute of limitations bars the claim.

III. ANALYSIS

A. Applicable Legal Standard

Section 300aa-16(a)(2) of the Vaccine Act provides that, regarding

> a vaccine set forth in the Vaccine Injury Table which is administered after [October 1, 1998], if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury.

42 U.S.C. § 300aa-16(a)(2).

This statute of limitations is not triggered by the administration of the vaccine, but "begins to run on the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury for which compensation is sought." *Cloer*, 654 F.3d at 1335. "[E]ither a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations],

[18] Briefing addressing Petitioner's request for interim attorneys' fees is not relevant to the timeliness issue and is therefore not included in this discussion.

whichever is first." *Markovich v. Sec'y of HHS*, 477 F.3d 1353, 1357 (Fed. Cir. 2007).

"[I]t is the first symptom or manifestation of an alleged vaccine injury, not first date when diagnosis would be possible, that triggers the statute of limitations." *Carson ex rel. Carson v. Sec'y of HHS*, 727 F.3d 1365, 1369 (Fed. Cir. 2013), *reh'g & reh'g en banc denied*, 2013 WL 4528833 at *1. "A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury." *Markovich*, 477 F.3d at 1357. While the symptom of an injury must be recognized as such "by the medical profession at large," *Cloer*, 654 F.3d at 1335, even subtle symptoms that a petitioner would recognize "'only with the benefit of hindsight, after a doctor makes a definitive diagnosis of injury,'" trigger the running of the statute of limitations, whether or not the petitioner or even multiple medical providers understood their significance *at the time*. *Carson*, 727 F.3d at 1369-70 (quoting *Markovich*, 477 F.3d at 1358).[19]

There is no explicit or implied discovery rule under the Vaccine Act. *Cloer,* 654 F.3d at 1337. The date of the occurrence of the first symptom or manifestation of onset of the alleged vaccine-related injury "does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition." *Id.* at 1339. Nor does it depend on when a petitioner knew or should have known of a potential connection between an injury and a vaccine. *Id.* at 1338 ("Congress made the deliberate choice to trigger the Vaccine Act statute of limitations from the date of occurrence of the first symptom or manifestation of the injury for which relief is sought, an event that does not depend on the knowledge of a petitioner as to the cause of an injury."); *see Markovich*, 477 F.3d at 1358 ("Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." (internal quotation marks omitted)).

[19] Petitioner argues that "POI is a latent injury" and that "the first symptom of onset, in terms of the applications [sic] of the statute of limitations, can be subtle and can precede manifestation of onset by months or even years." Pet'r's Post Hr'g. Br. at 9. This argument has been made before: the Court of Federal Claims, in *Setnes v. United States*, 57 Fed. Cl. 175 (2003), "was concerned with the very subtle symptoms attributed with autism that can be easily confused with typical child behavior, and it distinguished the terms 'symptom' and 'manifestation.'" *Markovitch*, 477 F.3d at 1357-58. The *Setnes* court's interpretation of the "first symptom or manifestation of onset" language of the statute was rejected by *Markovich*, a ruling that has since been reaffirmed by the Federal Circuit en banc in *Cloer*. 654 F.3d at 1334-1335.

B. Symptoms of POI Onset, Including Criteria for Distinguishing "Symptom" from "Normal"

Primary ovarian insufficiency can begin abruptly, *see* Tr. at 69; *see also* Nelson at 2-3; but it may also develop over several years, *see* Tr. at 70, 198-99, 398; *see also* Nelson at 2-3; Pet'r's Ex. 17, Tab 50 at 2 (Paolo Beck-Peccaz & Luca Persam, *Premature Ovarian Failure*, 1 Orphanet J. Rare Diseases, at 2 (Apr. 2006)) (hereinafter "Beck-Peccaz"). Thus, a woman could have symptoms of POI for several years before actually ceasing menstruation or being diagnosed with POI. *See* Tr. at 70, 198-99, 398*; see also* Tr. at 319; Nelson at 2-3; Beck-Peccaz at 2. The experts agreed that the symptoms of primary ovarian insufficiency include menstrual irregularities, including primary and secondary amenorrhea, cycle and frequency irregularity, and excessive or prolonged bleeding; delayed menarche; lack of breast development and poor growth velocity; night sweats; hot flashes; sleep disturbances; mood changes; recurring ovarian cysts; arrested puberty; and marked hirsutism. Tr. at 38, 57, 68-69, 319, 366. Most of these symptoms are not "normal" for a woman under the age of 40. Petitioner therefore does not dispute that they can constitute the "first symptom or manifestation of onset" of POI for purposes of the Act's statute of limitations, and there was little discussion of the symptoms beyond their inclusion on the list of symptoms. As to menstrual irregularities and delayed menarche, however, Petitioner and Petitioner's experts dispute that these two conditions should be considered symptoms at all, because many young women experience these conditions at the beginning of their reproductive lives, such that these conditions are considered "normal." *See, e.g.,* Pet'r's Post Hr'g Br. at 2, 4-8; Tr. at 32, 58, 61, 72-73, 170-71; *see also* Tr. at 380 (Respondent's expert, Dr. Frankfurter, explaining that it is normal for a teenager to have irregularity, albeit within a range). As a result, Petitioner and her experts claim, menstrual irregularity only constitutes a symptom or manifestation of onset of POI when that irregularity is effectively considered secondary amenorrhea. Pet'r's Post Hr'g Br. at 4-5; Pet'r's Post Hr'g Rep. Br. at 3.

By instead finding that "normal" menstrual irregularity is a symptom for purposes of the Act's statute of limitations, Petitioner argues, the undersigned will somehow increase Petitioner's burden of proof. *See* Pet'r's Post Hr'g Reply Br. at 1-2. The undersigned does not agree. The undersigned does agree, however, that to qualify as the first symptom or manifestation of onset under the Act, a condition must be a symptom of something amiss, however subtle; it cannot be "normal": a symptom is "[a]ny morbid phenomenon *or departure from the normal* in structure, function, or sensation, experienced by the patient and indicative of disease." Symptom, *Stedman's Medical Dictionary* (28th Ed. 2013) (hereinafter "*Stedman's*") (emphasis added); *accord Markovich*, 477 F.3d at 1360 (observing that eye blinking episodes constituting first symptom of child's seizure disorder "were not normal child behavior"). In order to determine the date of the first symptom or manifestation of onset of the vaccine-related

injury, therefore, a method for separating "normal" menstrual irregularities from abnormal symptoms of POI is necessary.[20]

Fortunately, medical literature provided by the parties provides a solution, both simple and elegant. *See* Resp't's Ex. A.2, ECF No. 57-4 (Comm. on Adolescent Health Care, Am. Coll. of Obstetricians & Gynecologists, *Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign*, Comm. Op. No. 349 (Nov. 2006)) (hereinafter "ACOG Opinion" or "ACOG Op."); *see also* Pet'r's Ex. 15, Tab 4. In *Cloer* and *Markovich*, the Federal Circuit directed that "the symptom or manifestation of onset must be recognized as such by the medical profession at large." *Cloer*, 654 F.3d at 1335; *Markovich*, 477 F.3d at 1360. The ACOG Opinion is an opinion from the Committee on Adolescent Healthcare at the American College of Obstetricians and Gynecologists, together with the American Academy of Pediatrics, entitled "Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign." *See* ACOG Op. It was issued in November 2006, and "Reaffirmed" in 2009. ACOG Op. at 1. The abstract of the ACOG Opinion provides:

> It is . . . important for clinicians to have an understanding of bleeding patterns in girls and adolescents, the ability to differentiate between normal and abnormal menstruation, and the skill to know how to evaluate young patients' conditions appropriately. Using the menstrual cycle as an additional vital sign adds a powerful tool to the assessment of normal development and the exclusion of serious pathologic conditions.

Id. The article goes on to discuss a number of articles and robust epidemiological studies concerning what constitutes "normal menstrual cycles in young females," including age at menarche, and "cycle length and ovulation," *id.* at 2-3; "abnormal menstrual cycles," including "prolonged interval[s]," *id.* at 3-4; and "excessive menstrual flow," *id.* at 4. The article concludes with a chart, reproduced below, that together with one difference applicable to women

[20] Petitioner also argues that irregular menstruation should not be considered the first symptom of POI because it "can be explained by other causes." Pet'r's Post Hr'g Reply Br. at 2-3. This argument has been repeatedly rejected by the Federal Circuit, and is equally as unpersuasive here. A symptom need not be exclusive to the particular injury alleged in order to be "the first symptom" of that injury for purposes of the Act. *See Markovich*, 477 F.3d at 1357 ("A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the significance of a symptom with regard to a particular injury."); *see also Carson*, 727 F.3d at 1370 (holding that even where "[t]here is no question that speech delay can be indicative of several conditions, and in some circumstances may even be normal . . . it was not arbitrary and capricious for the Chief Special Master to find that the severe speech delay . . . was the first objectively recognizable symptom of autism, the alleged vaccine injury.")

older than 18, provides comprehensive guidance to the "medical profession at large" about when menstrual irregularities have exceeded "normal" variation to become symptoms of a potential problem. *Id.* at 4-5. The chart is as follows:

Menstrual Conditions That May Require Evaluation

Menstrual periods that:

- Have not started within 3 years of thelarche[21]
- Have not started by 13 years of age with no signs of pubertal development
- Have not started by 14 years of age with signs of hirsutism[22]
- Have not started by 14 years of age with a history or examination suggestive of excessive exercise or eating disorder
- Have not started by 14 years of age with concerns about genital outflow tract obstruction or anomaly
- Have not started by 15 years of age[23]
- Are regular, occurring monthly, and then become markedly irregular[24]
- Occur more frequently than every 21 days or less frequently than every 45 days[25]

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[21] Thelarche is "the beginning of development of breasts in the female." Thelarche, *Stedman's*.

[22] Hirsutism is the "presence of excessive bodily and facial hair, usually in a male pattern, especially in women." Hirsutism, *Stedman's.*

[23] At the hearing, Doctors Hamiel and Gersh opined that an adolescent who has not reached menarche by age 16 should be evaluated for primary amenorrhea. Tr. at 92, 238. Dr. Frankfurter opined that the age of evaluation should be 15 years. Tr. at 365. Both the ACOG Opinion and Dr. Hillard, author of medical literature introduced by Petitioner, acknowledge that the traditional definition of primary amenorrhea has been no menarche by age 16. ACOG Op. at 2; Pet'r's Ex. 15, Tab 4, at 5, ECF No. 53-5 (Hillard, Paula, *Menstruation in Adolescents: What Do We Know? and What Do We Do with the Information?*, 27 J. Pediatric Adolescent Gynecology 309 (2014)) (hereinafter "Hillard" with pincites to Petitioner's pagination). However, both articles note that 95-98% of females will have experienced menarche by age 15, and that delays in evaluating these young women can result in delays in detection and treatment of significant disorders, including POI. ACOG Op. at 2; Hillard at 6.

[24] At the hearing, Dr. Hamiel testified that she would recommend further evaluation of a non-adolescent woman whose cycle had been regular (21-35 days) and then became irregular (less frequent than every 35 days). Tr. at 67.

[25] For women over the age of 18, this criterion is more frequently than every 21 days or less frequently than every 34 days. *See* ACOG Op. at 3; *see also* Tr. at 39 (documenting Dr.

- Occur 90 days apart even for one cycle[26]
- Last more than 7 days
- Require frequent pad or tampon changes (soaking more than one every 1-2 hours)

Id. at 5.

Hillard reproduces this chart, accompanied with this caution:

> Failure to evaluate teens who meet the criteria cited in the [ACOG] Opinion can be a significant disservice to young women, leading to unnecessary discomfort, embarrassment, poorer quality of life, adverse self esteem, and current or future health risks such as anemia and low bone mineral density, as well as potential metabolic and cardiovascular risks. . . . [J]ust as with other vital signs like pulse and respiration, *[menstrual cycle] values outside of statistically derived normal parameters may signal disease or derangements in normal health.*

Hillard at 8 (emphasis added).

There cannot be a better vehicle for the undersigned to use to sort out "normal" from "symptom" than one designed for that purpose by members of the medical profession themselves. Thus, the undersigned finds that for petitioners who were eighteen years old or younger at the time the condition arose, if the condition qualifies for evaluation on the ACOG chart, it constitutes a symptom for purposes of the Vaccine Act. For petitioners who were over eighteen years old at the time the condition arose, the chart also applies, except that periods that should be evaluated include those that occur more frequently than every 21 days or less frequently than every 34 days. *See* ACOG Op. at 3.[27]

Hamiel's testimony normal menstrual frequency for a woman in her twenties is 21-35 days). The undersigned interprets this criterion to apply to frequency over two or more cycles.

[26] At the hearing, Dr. Hamiel testified that no menstruation for 90 days is not "normal." Tr. at 79.

[27] To the extent Petitioner argues that this interpretation of the Vaccine Act's statute of limitations violates the Fifth Amendment on Equal Protection and Due Process Grounds, *see* Pet'r's Post Hr'g Br. at 11-13, the undersigned concurs with the reasoning articulated in numerous decisions to the contrary, all of which hold that the Act's statute of limitations does not violate the Constitution merely because it bars certain petitioners from bringing a claim before they knew, or even could have known, that their injuries were vaccine-related. *See, e.g.*, *Cloer v. Sec'y of HHS*, 85 Fed. Cl. 141, 150-51 (2008), *rev'd on other grounds*, 603 F.3d 1341, *aff'd en banc*, 654 F.3d 1322 (Fed. Cir. 2011); *Leuz v. Sec'y of HHS*, 63 Fed. Cl. 602, 607-12

Finally, as to contraceptives' impact on this analysis, Hillard specifically limited her discussion "only to bleeding on young women who are *not* taking any hormonal therapy such as birth control." Hillard at 6. All of the experts at the hearing agreed that hormonal therapy would mask POI symptoms. Tr. at 115, 161, 387-88. The ACOG Opinion recommends blood collection for screening before hormonal treatment is begun, ACOG Op. at 4, as did Doctors Hamiel, Tr. at 95-97, and Frankfurter, Tr. at 377, at the hearing; although, both experts acknowledged that such testing is often not performed before hormonal treatment is started. Tr. at 95-97, 112-13, 387-92.

Based on that information, the undersigned makes the following findings regarding how contraceptive use will inform the undersigned's findings on onset for purposes of the statute of limitations:[28]

1. If the form of contraceptive used was non-hormonal, i.e., a copper IUD without hormones,[29] condom/diaphragm, spermicide, the ACOG criteria apply as discussed above, without changes;
2. By definition, a contraceptive is "an agent that diminishes the likelihood of or prevents conception." Contraceptive, *Dorland's*. Therefore, if the medical records show that a hormonal contraceptive was prescribed for its primary purpose, that is, for contraception, rather than as treatment for menstrual irregularities; or if the medical records are silent as to the purpose of the prescription and the contraceptive use spanned the date on which the statute of limitations would have begun to run; the statute of limitations will not preclude the claim;
3. If the medical records indicate that the hormonal contraceptive was prescribed to treat menstrual irregularities, or if menstrual irregularities were a reason for the medical visit that resulted in the prescription of the contraceptive, then the undersigned will find that the menstrual irregularities were not "normal," but resulted in treatment, and therefore constituted a symptom for purposes of the statute of limitations.

(2005); *Wax v. Sec'y of HHS*, No. 03-2830V, 2012 WL 3867161, at *6-8 (Fed. Cl. Spec. Mstr. Aug. 7, 2012); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 655-57 (S.D. Tex. 2004); *Reilly ex rel. Reilly v. Wyeth*, 876 N.E.2d 740, 753-54 (Ill. App. Ct. 2007).

[28] This decision expresses no opinion concerning the effect, if any, of contraceptive use on the question of causation in a POI case.

[29] Dr. Frankfurther indicated that non-hormonal copper IUDs may affect the volume of flow but do not influence the cycle length or frequency. Tr. at 422.

C. Application of the Onset Symptom Criteria to the Present Case

Petitioner filed her petition on February 11, 2015. The petition is time-barred if "the first symptom or manifestation of onset" of her alleged vaccine injury, POI, occurred before February 11, 2012. Dr. Gersh opined that "[t]here is no indication of a symptom of premature ovarian failure . . . until [Petitioner] presented herself to her doctor in March 2012 indicating that she had not yet started menarche." Pet'r's Ex. 13 at 10, *Culligan*, ECF No. 47. Dr. Hamiel agreed with this assessment; she opined that the first symptom or manifestation of onset occurred within a few months of March 2012 when, at age 17, she reported to her pediatrician that she had never had a menstrual cycle. Pet'r's Ex. 15 at 14-15, *Culligan*, ECF No. 53; Pet'r's Ex. 3 at 38.

Because it is unclear whether Petitioner ever had a menstrual cycle in this case, the undersigned will assess timeliness based on two possible factual scenarios. According to notes taken by her pediatrician during a 14 year-old well-check visit on October 2, 2009, Petitioner had never had a menstrual cycle. Pet'r's Ex. 3 at 45. Because thelarche is documented to have occurred in 2006 and 2007, Petitioner's menstrual cycles were not yet "abnormal" under the ACOG Opinion as of the October 2009 visit. *See* Pet'r's Ex. 3 at 16 (noting that breast and pubic hair development occurred in 2006 and 2007, when Petitioner was 12 and 13 years old); ACOG Op. at 5 (identifying as "abnormal" menstrual periods that "have not started by 13 years of age with no signs of pubertal development"). Under this "never menstruated" scenario, the first symptom of Petitioner's POI would, therefore, have occurred by December 5, 2009, when Petitioner turned 15 years old without having had a menstrual cycle. *See* ACOG Op. at 5 (identifying as "abnormal" menstrual periods that "have not started by 15 years of age").

An alternative interpretation of the medical record reflects that Petitioner had sporadic menstrual cycles starting in approximately August of 2007, when Petitioner was 12 years old. *See* Pet'r's Ex. 3 at 43 (Pediatrician noting, on August 11, 2008, "Menses – X1? 1 yr ago"); Pet'r's Ex. 4 at 2 (geneticist Dr. Asamoah noting that "[w]hen [Petitioner] was approximately 12 to 13 years old, she experienced one day of spotting, but has not had a period since this time"). The next menstrual cycle is not documented until May 2013, when gynecologist Dr. Loveless noted that Petitioner "began to have vaginal bleeding in March lasting for about 9 days and spotting." Pet'r's Ex. 6 at 23. Dr. Loveless subsequently described the bleeding that occurred in March 2013, when Petitioner was 18 years old, as "spontaneous onset of menses." *Id*. at 24. Because the records reflect that Petitioner did not have a menstrual cycle between at least August 2007 and March 2013, the first symptom or manifestation of onset of her POI had occurred by November 2007, 90 days after her first cycle. *See* ACOG Op. at 5 (identifying as "abnormal" menstrual periods that "occur 90 days apart even for one cycle").

IV. CONCLUSION

Based on the foregoing analysis, the undersigned finds that the first symptom of Petitioner's injury occurred, at the latest, in December 2009. Because that date precedes the statute of limitations deadline by over two years, the undersigned concludes that Petitioner's claim is time-barred. Her petition therefore must be, and is hereby, **DISMISSED**.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.[30]

/s/ Lisa D. Hamilton-Fieldman
Lisa D. Hamilton-Fieldman
Special Master

[30] Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.